

**ACCOMPANYING LABELING:** Folder entitled "Directions for the use of Vital B-C Capsules.", reading in part: "Three capsules four times a day before meals and at bedtime."

**RESULTS OF INVESTIGATION:** The capsules in the above-described shipment were, after arrival at Philadelphia, Pa., repackaged into bottles and labeled as described above.

**LIBELED:** 6-4-58, E. Dist. Pa.

**CHARGE:** 502(a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for acne; and 502(j)—the article, because of its content of vitamin A, was dangerous to health when used in the dosage, and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Three capsules four times a day before meals and at bedtime," which were the recommended directions contained in the folder entitled "Directions for the use of Vital B-C Capsules."

**DISPOSITION:** 8-29-58. Consent—claimed by Daniel Cooperman Pharmacy, Philadelphia, Pa., and relabeled.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**5702. Clarimycin (3 seizure actions).** (F.D.C. Nos. 41607, 41608, 41609, 41610, 41677. S. Nos. 8-341 P, 11-763 P, 11-866/7 P, 16-789 P.)

**QUANTITY:** 1,912 display cards, each containing 1 btl., at Highland Park and Detroit, Mich.; 33 display cartons, each containing 6 btls., at Cleveland, Ohio; and 297 btls., at Pittsburgh, Pa.

**SHIPPED:** Between 12-12-57 and 2-24-58, from Jersey City, N.J., by Meritt Corp.

**LABEL IN PART:** (Btl.) "Contents 5 drams Clarimycin Anti-biotic Acne Lotion  
\* \* \* Active Ingredients: Neomycin Sulphate, Allantoin."

**LIBELED:** Between 3-3-58 and 4-23-58, E. Dist. Mich., W. Dist. Pa., and N. Dist. Ohio.

**CHARGE:** 502(a)—when shipped, the labeling of the article in the Cleveland and Pittsburgh lots contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, blackheads, and stubborn skin infections; and 505(a)—the article, in all lots, was a new drug which may not be introduced into interstate commerce, and an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** Between 8-21-58 and 10-21-58. Consent—destruction.

**5703. Meprobamate tablets.** (F.D.C. No. 41895. S. No. 4-401 P.)

**QUANTITY:** 1 drum containing 25,000 tablets at Richmond, Va.

**SHIPPED:** 5-6-58, from Brooklyn, N.Y., by Hall Pharmacal Co., Inc.

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained approximately 400 milligrams of meprobamate per tablet.

**LIBELED:** 6-27-58, E. Dist. Va.

**CHARGE:** 502(a)—the statement on the drum label "For Investigational and Export Use Only" was false and misleading as applied to the article; and 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 9-8-58. Default—destruction.

**5704. Meprobamate tablets.** (F.D.C. No. 41894. S. Nos. 29-956/7 P.)

QUANTITY: 3 drums containing a total of 512,000 tablets and one drum containing a total of 94,000 tablets at Brooklyn, N.Y.

SHIPPED: A quantity of meprobamate powder was shipped from East Paterson, N.J., and, after its arrival at Brooklyn, N.Y., was tableted and packed into the 3 drums described above. The 1 drum lot was a return shipment which was made on 6-4-58, from Philadelphia, Pa.

LABEL IN PART: (3 drum lot) "2-methyl-2-n-propyl-1, 3-propanediol dicarbamate. For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use. Caution: \* \* \* For Export Only"; (1 drum lot) "100,000 Tablets Meprobamate \* \* \* 400 Mg. \* \* \* Caution \* \* \* Dosage: 1 Tablet 3 times Daily. For investigational and export use only Hall Pharmacal Co., Inc., New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the article (both lots) contained approximately 400 milligrams of meprobamate per tablet.

Investigation showed that the article was not intended for export.

LIBELED: 7-7-58, E. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the statement on the label of the article "For manufacturing, processing, or repacking in the preparation of a new drug limited by Federal law to investigational use \* \* \* For Export Only" was false and misleading; and 505(a)—the article was a new drug, and an application filed pursuant to 505(b) was not effective with respect to such drug.

DISPOSITION: 3-26-59. Consent—destruction.

**5705. Meprobamate tablets and meprobamate powder.** (F.D.C. No. 41764. S. Nos. 62-771 M, 29-942 P.)

INFORMATION FILED: 9-23-58, Dist. N.J., against Abraham J. Schwartz, Jersey City, N.J.

SHIPPED: *Meprobamate tablets* were shipped on 3-26-57, and *meprobamate powder* was shipped on 3-8-57, from New Jersey to New York.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e) (1)—the labeling of the articles failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the articles failed to bear adequate directions for use; 502(i)—the *meprobamate tablets* were (2) an imitation of another drug, namely, Miltown, and (3) were offered for sale under the name of another drug, namely, Miltown; and 503(b) (4)—the labeling of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505(a)—the *meprobamate tablets* were a new drug, and an application filed pursuant to the law was not effective with respect to the drug.

PLEA: Guilty.

DISPOSITION: 5-22-59. \$1,800 fine and probation for 5 years.

**5706. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 39431. S. No. 52-010 M.)

QUANTITY: 52 vials at Brooklyn, N.Y.

SHIPPED: 5-21-56, from Chicago, Ill., by Medical Chemicals Corp.